DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

5272

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

March 13, 2001

Ref: 2001-DAL-WL-12

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Phillip P. Janca, Chairman
Hyperbaric Technologies, Inc. (HyperTec)
301 E. Main Street
Olney, Texas 76374

Dear Mr. Janca:

During an inspection of your firm located in Olney, Texas on December 7, 12 through 14, 2000, our investigator determined that your firm manufactures the Model 3200 Hybrid Monoplace and Model 5000 Multiplace Hyperbaric Oxygen Therapy systems and accessories. These products are medical devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The law requires that device manufacturers conform to the Quality System (QS) Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The inspection documented significant deviations from the Current Good Manufacturing Practice (CGMP) requirements for devices; therefore, your devices are adulterated pursuant to Section 501(h) of the Act.

Our review of the inspection revealed that your firm had failed to establish and maintain many requirements of the Quality System Regulation. As such, you are required to take immediate corrective actions to bring your firm's quality systems into compliance with the law. The violations include, but are not limited, the following:

1. Failure of the management with executive responsibility to ensure that an adequate and effective quality system has been established and maintained [21 CFR 820.20]. For example:

   (a) Device history records are incomplete and lack manufacturer's data report for pressure vessels for human occupancy, electrical safety test report, pneumatic test record, and certificate of completion [FDA-483 Items 1,2, 3, 6].

(b) 24 of the 27 manufacturing and quality system procedures, as listed in the quality manual, were missing.

(c) Internal self-audits have not been conducted.

2. Failure to maintain adequate device history records to demonstrate that the device is manufactured in accordance with the device master record [21 CFR 820.184]. For example, the device history records lack records of review and approval, release of device labeling, manufacturer's data report for pressure vessels for human occupancy, electrical safety test report, pneumatic test record, and certificate of completion [FDA-483 Items 1, 2, 3, 6].

3. Failure to maintain a complete device master record [21 CFR 820.181]. For example:

(a) Labeling specifications, such as the required prescription label and the serial number tag, are not included in the device master record [FDA-483 Item 4].

(b) Even though Model 3200 and 5000 hyperbaric chambers have been commercially distributed, their Operations and Maintenance Manuals (provided to our investigator at the time of the inspection) are still in the "DRAFT" form and have not been approved and signed off by your management since the release of their initial version on September 1, 2000.

4. Failure to maintain adequate installation of the device [21 CFR 820.170]. For example, a Model 5100-9909 hyperbaric chamber used to treat patients at the firm was not located in a designated area dedicated only for the hyperbaric oxygen therapy as instructed in the Chamber Operations and Maintenance Manual [FDA-483 Item 8].

5. Failure to establish and maintain procedures to control the design of the devices [21 CFR 820.30]. For example, design history files have not been established and maintained [FDA-483 Item 5].

6. Failure to conduct internal quality audits [21 CFR 820.22]. The inspection revealed that there was no documentation of self-audits of the firm's quality systems since the start of the firm's manufacturing.

The law also requires that manufacturers of medical devices obtain marketing clearance for their products from the FDA before they can offer them for sale. This helps protect the public health by ensuring that newly introduced medical devices are safe and effective for their intended uses. We are very concerned that you are promoting your hyperbaric oxygen therapy systems for numerous diseases and conditions for which you have not obtained marketing clearance.

On December 6, 2000, FDA notified you that your Model 3200 Monoplace (510(k) submission K002795) and Model 5000 Multiplace Hyperbaric Oxygen Therapy Systems (510(k) submission K002794) could be marketed as prescription devices for the treatment of the following diseases and conditions:

Air or Gas Embolism;
Carbon Monoxide Poisoning or Carbon Monoxide Poisoning Complicated by Cyanide Poisoning;
Clostridial Myositis and Myonecrosis (Gas Gangrene);
Crush Injury, Compartment Syndrome, and other Acute Traumatic Ischemias;
Decompression Sickness;
Enhancement of Healing in Selected Problem Wounds;
Exceptional Blood Loss (Anemia);
Intracranial Abscess;
Necrotizing Soft Tissue Infections;
Osteomyelitis (Refractory);
Delayed Radiation Injury (Soft Tissue and Bony Necrosis);
Skin Grafts and Flaps (Compromised); and
Thermal Burns.

Our review of your firm's websites, including www.hyperbaric-therapy.com, www.hyperbaric-health.com, www.hypertec-o2.com, www.hyperbaric-chamber.com, www.hyperbaric-forum.com, www.oxygen-chamber.com, www.american-hyperbaric.com, and www.midsouthhbot.com , www.hvhbot.com revealed that you have made a major modification in the intended use of the Model 3200 Monoplace and Model 5000 Multiplace Hyperbaric Oxygen Therapy Systems. The "intended use" of a device is not only determined from it's labeling, but also from how the device is advertised, from the oral or written statements made about the device, and from the manner in which the device is distributed (See 21 CFR 801.4). Your firm's websites and links from your websites promote hyperbaric oxygen therapy and your devices for numerous additional diseases and conditions, for which you have not received clearance from the agency. These include:

AIDS;
Autism;
Multiple Sclerosis;
Myocardial Infarction;
Near Drowning;
Brown Recluse Spider Bites;
Cerebral Palsy;
Closed Head Injuries;
Chronic Fatigue Syndrome;
Lyme Disease;
Macular Degeneration;
Reflex Sympathetic Dystrophy (RSD) Syndrome;

Sports Injuries;
Stroke; and
Traumatic Brain Injuries.

Because these are major modifications in the intended use of your devices, you are required to submit new 510(k)s (See 21 CFR 807.81(a)(3)(ii)). Because you have not submitted 510(k)s for these uses, your hyperbaric oxygen therapy systems are misbranded under Section 502(o) of the Act. Until such time as you submit 510(k)s and obtain FDA clearance for the new intended uses, your hyperbaric oxygen therapy systems are also adulterated under Section 501(f)(1)(B) of the Act, in that they are Class III devices under Section 513(f) and do not have an approved applications for premarket approval (PMA) in effect pursuant to Section 515(a), or approved applications for investigational device exemption (IDE) under Section 520(g).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or assessing civil money penalties. Also, until these violations are corrected, and FDA has documentation to establish that such corrections have been made, federal agencies will be advised of the issuance of this Warning Letter so that they may take this information into account when awarding government contracts.

In addition to the Federal Food, Drug, and Cosmetic Act, you may also be subject to provisions of the Federal Trade Commission Act, which prohibit deceptive acts or practices in or affecting commerce, and the dissemination of any false advertisement to induce the purchase of a food, drug, or device (See Sections 52 and 45 of Title 15 of the United States Code).

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Your reply should be directed to Mr. Thao Ta, Compliance Officer, at the above letterhead address.

Sincerely yours,

Michael A. Chappell
Dallas District Director

cc: [redacted]

Mr. Todd Janca
Hyperbaric Technologies, Inc. (HyperTec)
301 E. Main Street
Olney, Texas 76374